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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/808,574

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Arkady Glukhovsky

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EXAMINER

SMITH, PHILIP ROBERT

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

04/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/808,574	Applicant(s) GLUKHOVSKY, ARKADY	
	Examiner PHILIP R. SMITH	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-46 is/are pending in the application.
- 4a) Of the above claim(s) 21-34 and 36-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-20 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restriction

- [01] Newly submitted claims 36-46 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the apparatus as claimed can be used to practice another and materially different process. In this case, the apparatus of claim 1 can be used to image a second in vivo segment prior to detaching the detachable appendage.
- [02] Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 36-46 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

- [03] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- [04] Claims 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross (2004/0253304) in view of Iddan (2003/0214580).
- [05] With regard to claim 11: Gross discloses an ingestible imaging device comprising:
- [05a] an imaging device ("camera" [0075]) having a housing ("biologically inert housing 32" [0350]); and
- [05b] a detachable appendage (comprising "film 46A" and "drug 36A" [0367]), wherein the housing and the detachable appendage form an oblong capsule shape (see Figure 15) when joined together.

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- [06] Gross does not disclose that the housing ("32" as noted above) is substantially spherical. Iddan discloses a capsule endoscope which "may have a body shaped as for example a capsule or elongated member... Other suitable shapes and sizes, such as spherical, ellipsoid, etc., may be used, depending on the application" ([0022]). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to construct the sheath of Gross in whatever shape is efficacious. Iddan shows that a sphere is known to a skilled artisan.
- [07] With regard to claims 12-13: Iddan (5,604,531), which is incorporated into Gross (as directed in [0039]), discloses an illumination source ("light source 20," 3/29) and a transmitter ("transmitter 28," 3/31). The illumination source inherently has intensity that is adjustable in vivo.
- [08] With regard to claim 14: Gross inherently discloses a ballast weight.
- [09] With regard to claims 15-16: The "film 46A" disclosed by Gross is inherently a degradable material that is pH sensitive.
- [10] With regard to claims 17-20: The "film 46A" anticipates dissolvable glue. It comprises an outer coating ("46A" as noted above) and an internal filling ("drug 36A" as noted above). It is dissolvable, as noted above, and thus is inherently semi-permeable.

Additional Claim Rejections - 35 USC § 103

- [11] Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gross (2004/0253304) in view of Iddan (2003/0214580) and in further view of Yokoi (2003/0181788).
- [12] With regard to claim 35: As noted above, Gross discloses an imaging device ("camera" [0075]) which inherently has an imaging axis. Gross discloses an oblong capsule shape (see Figure 15) which inherently has an oblong axis. Gross does not disclose that the imaging axis is "aligned with" the imaging axis.

- [12a] Note: The phrase “aligned with” does not appear in the specification. In accordance with the figures and the plain meaning of the word “align”, the claim is interpreted to mean that the imaging axis and the oblong axis are *coincident*. Axes which are parallel but non-coincident, such as those disclosed by Gross (see Figure 30), are interpreted as being outside of the scope of claim 35, since they are not “aligned”. Therefore, Gross does not disclose that the imaging axis is “aligned with” the imaging axis.
- [13] Yokoi discloses an ingestible imaging device having an oblong capsule shape. The device has a “longitudinal center axis 38” (see Figures 6B and 7B) which coincides with an imaging axis of the imaging device and an oblong axis of the capsule. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to place the “camera 242” disclosed by Gross in Figure 30 along a longitudinal center axis of the capsule. A skilled artisan would be motivated to do so for several possible reasons:
- [13a] To prevent image translation due to rotation of the capsule.
- [13b] To provide a center of gravity which is coincident with the oblong axis.
- [13c] To provide the largest possible field of view, i.e. one in which all sides of a lumen through which an oblong capsule travels are viewable.

Response to Arguments

- [14] Applicant's arguments filed 2/12/08 have been fully considered but they are not persuasive.
- [15] Applicant contends that
- ...the drugs 46A, 46B, and 46C [which have been used to formulate the rejection] are released on a time-basis alone. There is no actuated driving mechanism (such as depicted in Fig. 21, etc.), and therefore, there is no need for a camera to capture images and determine the location to actuate the driving mechanism for drug release.

[16] On the contrary, the camera disclosed by Gross is presented as an addition or alternative to a timer.

See [0075] or [0472]-[0473]. In [0075], Gross states explicitly that

...the functionality for activating the driving mechanism, described hereinabove as being provided by a coating, is supplemented or replaced by other activating functionalities... Alternatively or additionally, the capsule comprises a camera, which records an image of the GI tract for on-board analysis and, if appropriate, activation of the driving mechanism in response to the image.

[17] Applicant further contends that "the Examiner provides no motivation to one of ordinary skill to modify the Gross reference to make the capsule spherical". However, Iddan clearly shows that ingestible imaging devices may be constructed of any available shape, including spheres. Common sense dictates that an ingestible device have rounded edges. A sphere fits this criteria, as Iddan suggests. In reciting *KSR v. Teleflex*, Applicant correctly notes that "one of the ways" in which obviousness can be shown is "by noting that there existed at the time of the invention a known problem for which there was an obvious solution". *KSR v. Teleflex* also notes that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results" (page 12). In this case, the familiar elements include the capsular camera housing with detachable appendage disclosed by Gross; and the spherical camera housing disclosed by Iddan. It is maintained that the apparatus of claim 11 is an obvious combination of familiar elements; and that no result of this combination would be unpredictable to a person of ordinary skill.

Conclusion

[18] Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

- [19] A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.
- [20] Any inquiry concerning this communication or earlier communications from the examiner should be directed to PHILIP R. SMITH whose telephone number is (571)272-6087 and whose email address is philip.smith@uspto.gov. The examiner can normally be reached between 9:00am and 5:00pm.
- [21] If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272 4764.
- [22] Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Philip R Smith/

Examiner, Art Unit 3739

/Linda C Dvorak/

Supervisory Patent Examiner, Art Unit 3739